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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Meeting Summary: April 26, 2002 Presentation by the Fluoropolymer Manufacturing Group to EPA

FROM: Charles M. Auer, Director
Chemical Control Division

TO: Administrative Record File AR-226: PFOS, PFOA, Telomers & Related Chemicals

On April 26, 2002, the Fluoropolymer Manufacturing Group (FMG) met with EPA to provide an update on FMG's research program concerning perfluorooctanoic acid (PFOA) and ammonium perfluorooctanoate (APFO), and to present information on the production, use, and possible exposure pathways for PFOA and APFO. Copies of FMG's slide presentation and the attendance list for the meeting are available in AR-226.

Prior to and again at the start of the meeting, EPA noted that it would not discuss the two-generation reproductive study in rats that had been submitted to AR-226 shortly before the meeting, because the Agency had not completed its review of the study.

FMG presented several slides summarizing and interpreting serum data from rat and monkey toxicity studies on PFOA. FMG concluded that serum levels are not a reliable indicator of cumulative internal dose for use in human health risk characterization. FMG accordingly recommended that EPA use standard risk characterization procedures to assess the potential risk to humans, working from external dose in the animal model with the application of appropriate uncertainty factors, rather than calculate a margin of safety based on the levels of PFOA measured in human serum. In discussion on the rat serum data, FMG reported that the rats were sampled only once, 24 hours after their last dose. EPA questioned FMG's dismissal of the serum level data, and noted that the information on the slides, being based on a single 24-hour sample, was not sufficient to support FMG's categorical conclusion. EPA also questioned the use of a serum concentration clearance curve that was presented as being illustrative, but that did not represent actual data.

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With respect to the possible sources of exposure to PFOA/APFO from manufacturing, FMG presented slides indicating that there has been a reduction of about 40% in U.S. APFO manufacturing capacity, a reduction of about 98% in emissions, and a virtual elimination of domestic manufacture for non-fluoropolymer uses. In discussion on the slides, FMG indicated that new plants built to replace capacity lost to 3M's withdrawal from the market implemented a product stewardship initiative and employed new control technologies that the old plants didn't have, leading to the drop in emissions. FMG noted that the new capacity in the U.S. was limited by permit levels, and that all of the U.S. production would be restricted to sales only to responsible users in the fluoropolymer industry, eliminating releases from any other users. FMG members indicated that they believed that the U.S. capacity will satisfy U.S. needs, and that much of the reduction in U.S. capacity could be attributed to the discontinuance of 3M production exported to Japan.

In response to questions from the EPA on the slides, FMG reported that it would have a better idea by the middle of the year on the needs of the fluoropolymer industry for APFO and on the extent to which those needs would be satisfied by U.S. production and by importation from other countries. FMG indicated that it had requested information from users of its fluoropolymer dispersions in order to assemble a mass balance for the industry, but that it had gotten little response. FMG reported that it was working to communicate with users on the importance of the data and to set up a third party collection system both to protect confidential data and to provide assistance to user companies in completing the data forms. EPA noted that this did not take into account the possible importation of APFO by non-fluoropolymer companies for other uses, but acknowledged FMG's assertion that such other uses historically constituted only a very small percentage of APFO consumption.

Addressing possible exposure sources other than releases from APFO manufacturing or from plants utilizing fluoropolymer dispersions, FMG presented a slide indicating that some perfluorooctanesulfonyl fluoride (POSF)-related products produced by 3M had PFOA contamination at low levels. The slide also noted that a recent 3M study showed a correlation between PFOS and PFOA levels in human blood. EPA questioned the slide as it appeared to attribute the human PFOA blood levels directly to PFOA contamination of 3M PFOS-based products. FMG members acknowledged that the two items were not related and should not have been placed on the same slide. FMG asserted that the PFOA impurity information was found in publicly available documents in AR-226, but did not provide a citation to any specific document in which the supporting statement might be located.

FMG indicated that it would be performing additional blood analysis work. In that discussion, EPA asked specifically whether an effort would be made to look for higher and lower homologues, as well as for the presence and amount of branched versus linear PFOA structures. EPA noted that, according to the information presented, most APFO used historically was produced by electrochemical fluorination (ECF), which FMG members indicated was about 25% branched and 75% linear, while the telomer-produced variety was entirely linear. EPA observed that production was now converting from the ECF process to the telomerization one exclusively. EPA stressed that it would be important to get a picture now, if possible, of what is currently

present in humans, since that might provide an important clue to the source of the PFOA which now exists as a human body burden. EPA acknowledged that this datum may or may not be informative, depending upon what is found. EPA observed, however, that it could be very important, especially if data pointed not only toward ECF manufacturing releases, but also toward straight-chain telomer degradation as a potentially significant source of the current PFOA levels. FMG emphasized that its member companies represented manufacturers and users of fluoropolymer dispersions, not telomers, and indicated that direct telomer-related information should be sought from the members of the Telomer Research Project group.

FMG reported that the rest of its ongoing toxicity and environmental fate testing activities were continuing and remained essentially on schedule. EPA agreed that another meeting could be planned at such time as FMG had additional data to report, but no schedule was set.